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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,909	02/27/2004	Helge Lubenow	QGN-004.0 US-2	7522
29425	7590	01/31/2006	EXAMINER	
LEON R. YANKWICH YANKWICH & ASSOCIATES 201 BROADWAY CAMBRIDGE, MA 02139			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/788,909	<b>Applicant(s)</b> LUBENOW ET AL.	
	<b>Examiner</b> Jeffrey Fredman	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,33,34 and 67-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,33,34 and 67-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/18/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status***

1. The art unit and examiner for this application has changed. The application has been returned to the examiner who completed examination after the BPAI decision on the parent application.

### ***Election/Restrictions***

2. The restriction requirement is entirely withdrawn since the groups are not distinct and there is no burden of search in this case, where the method is virtually identical between the different claims and the different "groups". All pending claims will be examined.

### ***Claim Interpretation***

3. The main issue open for interpretation is the limitation of separating particles "while minimizing particle loss". This limitation simply represents an intended use, which is not given patentable weight with respect to the 102 rejections. As noted in the decision of the BPAI on the parent application, 09/353,407, "It is well established that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. See *In re Woodruft* 919 F.2d 1575, 1577, 16 USPQ 2d 1934, 1936 (Fed. Cir. 1990)."

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 33, 34 and 67-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiscox et al (Virus Research (1995) 36:119-130).

Hiscox et al teaches a method of claims 1, 2, 67, 68, of separating particles (see page 122, section 2.3) comprising the steps:

a) combining a solution of total cellular RNA with 0.1% SDS with magnetic beads (see page 122, section 2.3, where the magnetic beads meet the affinity particle limitation as shown by page 2 of the specification, which specifically refers to magnetic beads and by claim 75),

b) collecting the particles of the particulate matrix material (see page 122, section 2.3, where Hiscox teaches washing of the particles, which inherently requires collection since the particles cannot be washed without collection and separation from the washing buffer),

c) separating the supernatant from the particulate matrix material (see page 122, section 2.3, where Hiscox teaches elution of the RNA, and removal for ethanol precipitation).

With regard to claims 33, 34, Hiscox teaches the use of SDS in the incubation step, as well as in the washing steps (see page 122, section 2.3).

It should be noted that Hiscox teaches the optional resuspending and eluting steps at page 122, step 2.3, since the washing step will inherently involve resuspending the beads in the wash buffer and a final elution is performed.

With regard to claims 68-75, Hiscox teaches a concentration of 0.1% SDS, which falls between 0.05% and 1% (see page 122, section 2.3).

With regard to claims 71-74, Hiscox teaches washing, which will disperse the particles, as required by claim 33 (see page 122, section 2.3).

With regard to claim 75, Hiscox teaches magnetic particles (see page 122, section 2.3).

6. Claims 1, 2, 33, 34 and 67-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Burg (U.S. Patent 5,780,273).

Burg teaches a method of claims, 1, 2, 67 and 68 of separating particles (see page 122, section 2.3) comprising the steps:

a) combining a solution of DNA targets with a blocking buffer that comprised 0.5% Sarkosyl (see column 16, line 51) with magnetic beads (see column 18, lines 37-52, where the magnetic beads meet the particle limitation as shown by claim 75, which specifically claims these as a species of particle),

b) collecting the particles of the particulate matrix material (see column 18, lines 48-52, where Burg teaches collection of the ternary complexes),

c) separating the supernatant from the particulate matrix material (see column 18, line 52, where Burg teaches aspiration of the supernatant).

With regard to claims 33, 34, Burg teaches the use of Sarkosyl in the incubation step as well as in the washing steps(see column 18, lines 37-61).

With regard to claims 68-75, Burg teaches a concentration of 0.5% Sarkosyl, which falls between 0.05% and 1% (see column 16, line 51).

With regard to claims 71-74, Burg teaches washing, which will disperse the particles, as required by claim 33 (see column 18, lines 53-61).

With regard to claim 75, Burg teaches the use of magnetic particles (see column 16, lines 61, for example).

7. Claims 1, 2, 33, 34 and 67-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Dale et al (U.S. Patent 5,856,092)

Dale et al teaches a method of claims 1, 2, 67 and 68 of separating particles (see column 29, lines 19-31) comprising the steps:

a) combining about 10 microliters of a BSP-1 solution with 100 microliters of a solution comprising 0.1% SDS with magnetic beads (see column 29, lines 20-25, where the magnetic beads meet the particle limitation as shown by claim 75, which specifically claims these as a species of particle),

b) collecting the particles of the particulate matrix material (see column 29, lines 26-28, where Dale teaches magnetic concentration of the particles),

c) separating the supernatant from the particulate matrix material (see column 29, lines 25-26, where Dale teaches removal of the supernatant).

With regard to claims 33, 34, Dale teaches the use of SDS in the incubation step and washing steps (see column 29, line 20-30).

With regard to claims 68-75, Dale teaches a concentration of about 0.1% SDS, which falls between 0.05% and 1% (see column 28 to column 29).

With regard to claims 71-74, Dale teaches washing, which will disperse the particles, as required by claim 33 (see column 29, lines 25-31).


With regard to claim 75, Dale teaches the use of magnetic beads (see column 29, line 19-30, where the Dynal M-280 beads are magnetic beads).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

1/27/06